Complete Summary

GUIDELINE TITLE

Practice parameters for the use of laser-assisted uvulopalatoplasty: an update for 2000.

BIBLIOGRAPHIC SOURCE(S)

Littner M, Kushida CA, Hartse K, Anderson WM, Davila D, Johnson SF, Wise MS, Hirshkowitz M, Woodson BT. Practice parameters for the use of laser-assisted uvulopalatoplasty: an update for 2000. Sleep 2001 Aug 1;24(5):603-19. [57 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Snoring
- Obstructive sleep apnea (OSA)

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Neurological Surgery Otolaryngology Sleep Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To assist practitioners in determining the appropriateness of laser-assisted uvulopalatoplasty
- To update the 1994 practice parameters for the use of laser-assisted uvulopalatoplasty

TARGET POPULATION

Adults who snore

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Laser-assisted uvulopalatoplasty (LAUP)
- 2. Conventional uvulopalatopharyngoplasty (UPPP)

MAJOR OUTCOMES CONSIDERED

- Reduction of snoring as measured by subjective criteria
- Reduction of sleepiness
- Post-laser-assisted uvulopalatoplasty (LAUP) polysomnography to evaluate improvement in the indices measuring obstructive sleep apnea (OSA) (i.e., apnea/hypopnea indices; sleep fragmentation, daytime sleepiness, respiratory disturbance index, continuous pharyngeal and esophageal pressure measures with a nasal tube containing 6 pressure sensors)
- Multiple sleep latency test results
- Adverse effects of laser-assisted uvulopalatoplasty

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches using the MEDLINE (1966-present) database as the primary source, as well as hand-searches of other appropriate texts.

Medline searches for articles on laser-assisted uvulopalatoplasty were conducted through September 2000. Key words for the search included LAUP, laser-assisted uvulopalatoplasty, laser-assisted uvulopalatoplasty, laser surgery, somnoplasty, base of the tongue reduction, uvulopalatopharyngoplasty (UPPP), uvulopalatoplasty, uvulopalatoplasty, uvulopalatopharyngoplasty (upper apple ap

and upper airway surgery. Articles in all languages were considered for inclusion, and were screened based on their English-language abstracts. Upon review of articles that were considered for inclusion, additional references were discovered by pearling (i.e., the process of selecting relevant articles referenced in the original article). These were references located in publications not typically found through Medline. The types of these publications include books, course books, meeting and symposium abstracts or proceedings, highly specific or trade journals.

NUMBER OF SOURCE DOCUMENTS

The number of source documents used for each corresponding category is listed below:

- Medline articles obtained and examined at full length after identification of 123 potentially relevant articles = 90
- Books = 6
- Course book = 1
- Meeting and symposium abstracts or proceedings = 8
- Highly specific or trade journals = 30

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Recommendation Grades

A (Evidence Level I)

• Randomized well-designed trials with low-alpha & low-beta errors*

B (Evidence Level II)

Randomized trials with high-beta errors*

C (Evidence Level III)

Nonrandomized controlled or concurrent cohort studies

C (Evidence Level IV)

Nonrandomized historical cohort studies

C (Evidence Level V)

Case series

* Alpha error refers to the probability (generally set at 95% or greater) that a significant result (e.g., p < 0.05) is the correct conclusion of the study or studies. Beta error refers to the probability (generally set at 80% or 90% or greater) that a nonsignificant result (e.g., p > 0.05) is the correct conclusion of the study or studies. The estimation of beta error is generally the result of a power analysis. The power analysis includes a sample size analysis which projects the size of the study population necessary to ensure that significant differences will be observed if actually present.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Articles entered into the evidence tables (see Tables 1 and 2 in the original guideline document) included randomized trials and nonrandomized controlled or concurrent cohort studies on the comparison with uvulopalatopharyngoplasty for snoring and obstructive sleep apnea (see Table 1 in the original guideline document) and peer-reviewed case series and historical cohort studies on the efficacy of laser-assisted uvulopalatoplasty for obstructive sleep apnea (see Table 2 in the original guideline document), with a minimum of five patients and a clearly defined outcome that could be used to adequately assess the therapy. In the case of the peer-reviewed case series and historical cohort studies entered in Table 2 (see original guideline document), studies were included only if the "effect size" (see Table 3 in the original guideline document) or the overall effect of laser-assisted uvulopalatoplasty on the number of respiratory events during sleep could be derived from the article. Articles describing nonrandomized historical cohort studies (13), case series (45), and other studies (69) derived from the search were found useful as background articles.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When scientific data were insufficient or inconclusive, recommendations were based on consensus opinion.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Levels of Recommendation

Standard

 This is a generally accepted patient-care strategy which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.

Guideline

• This is a patient-care strategy which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.

Option

• This is a patient-care strategy which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Board of Directors of the American Academy of Sleep Medicine reviewed the Standards of Practice Committee (SPC) for material conflicts of interest relevant to the recommendations and approved the final version of the parameters prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations are given as standards, guidelines, and options as defined below. The recommendation grades (A-C) and levels of evidence (I-V) are defined at the end of the Major Recommendation field.

Levels of Recommendation

Standard

This is a generally accepted patient-care strategy that reflects a high degree
of clinical certainty. The term standard generally implies the use of Level I
Evidence, which directly addresses the clinical issue, or overwhelming Level II
Evidence.

Guideline

• This is a patient-care strategy that reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.

Option

- This is a patient-care strategy that reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.
- 1. Laser-assisted uvulopalatoplasty is not recommended for the treatment of the sleep-related breathing disorders including obstructive sleep apnea. (Guideline)

There is insufficient evidence to recommend laser-assisted uvulopalatoplasty for the treatment of the obstructive sleep apnea syndrome. The Level V, Grade C evidence from seven articles indicates that laser-assisted uvulopalatoplasty provides a small overall decrease in apnea/hypopnea index in a group of patients, that preoperative prediction strategies for selecting patients who respond have not been developed, that some patients may have an increase in apnea/hypopnea index, and that there is insufficient information on other outcome measures or long-term efficacy. Therefore, the guideline developer does not recommend laser-assisted uvulopalatoplasty for the treatment of obstructive sleep apnea. This recommendation is similar to a recommendation of the previous practice parameter paper.

2. Laser-assisted uvulopalatoplasty is not recommended as a substitute for uvulopalatopharyngoplasty in the treatment of sleep-related breathing disorders including obstructive sleep apnea. (Guideline)

There are three studies with Level III, Grade C evidence on comparison including measurement of apnea/hypopnea index or airway size. When considered in conjunction with the small effect size of laser-assisted uvulopalatoplasty on apnea/hypopnea index, these studies provide insufficient evidence to indicate that laser-assisted uvulopalatoplasty is an acceptable substitute for uvulopalatopharyngoplasty with respect to either effectiveness or side effect profiles as a treatment for obstructive sleep apnea. This is a new recommendation.

3. Laser-assisted uvulopalatoplasty appears comparable to uvulopalatopharyngoplasty in relieving subjective snoring. (Guideline)

There are 4 Level III, Grade C studies that compare laser-assisted uvulopalatoplasty to uvulopalatopharyngoplasty for snoring. These studies suggest that laser-assisted uvulopalatoplasty can reduce snoring measured by subjective criteria to a similar degree as uvulopalatopharyngoplasty. This is a new recommendation.

4. Surgical candidates for laser-assisted uvulopalatoplasty as a treatment for snoring should undergo a preoperative clinical

evaluation and a polysomnographic or a cardiorespiratory study (Ferber et al., 1994; Standards of Practice Committee of the American Sleep Disorders Association, 1994; Indications for Polysomnography Task Force, American Sleep Disorders Association, 1997) to determine if the candidate has a sleep-disordered breathing disorder including obstructive sleep apnea. (Standard)

Since snoring is a primary diagnostic symptom, patients who undergo laser-assisted uvulopalatoplasty should be informed of the need for periodic evaluation for subsequent development of obstructive sleep apnea even if the procedure reduces or eliminates snoring. (Standard)

These recommendations are based on information regarding the natural course of obstructive sleep apnea. Snoring may predate onset of obstructive sleep apnea, as well as other symptoms of obstructive sleep apnea such as excessive daytime sleepiness. Although snoring is neither necessary nor sufficient for the diagnosis of a sleep-related breathing disorder, it is frequently an associated symptom. It is estimated that the occurrence of obstructive sleep apnea ranges from 25% to as high as 95% in snorers. In one study that reviewed patients seeking laser-assisted uvulopalatoplasty treatment specifically for snoring, 95% had obstructive sleep apnea by polysomnography. The presence of other risk factors for sleep apnea such as obesity and age, as well as other associated symptoms such as daytime sleepiness and witnessed breathing pauses, increase the risk for concomitant sleep apnea. Given the life-threatening conditions (e.g., myocardial infarction, cardiac failure, stroke) associated with sleep-related breathing disorders and the increased risk for motor-vehicle or industrial accidents secondary to the daytime sleepiness related to sleep-disordered breathing, it is prudent to test for these disorders. Patients who elect to undergo laser-assisted uvulopalatoplasty for the treatment of snoring may also be at risk of incurring a delay in the diagnosis of obstructive sleep apnea because snoring may be reduced or eliminated by laser-assisted uvulopalatoplasty. Thus, after laserassisted uvulopalatoplasty for treatment of snoring, the patient should be notified regarding the possibility of developing obstructive sleep apnea, and should be monitored for the occurrence of this disorder. These recommendations are similar to recommendations of the previous practice parameter paper.

5. The need for medications that affect respiration during the perioperative period should be assessed during the preoperative clinical evaluation. (Standard)

This recommendation is based on consensus of the American Academy of Sleep Medicine (AASM) Standards of Practice Committee. The perioperative use of narcotics may pose risks for patients who have undergone laser-assisted uvulopalatoplasty operations; therefore, the need for these medications should be carefully assessed during the preoperative clinical evaluation. Careful clinical judgment should be used when prescribing other pain medications, sedatives, sleeping pills and alcohol during the perioperative period. The rationale is that these medications may blunt respiratory drive. This is especially important since postoperative swelling

may reduce the caliber of an already narrowed airway. Alternatives, such as oral or topical non-narcotic pain medications during the perioperative periods, should be used whenever possible, and hypnotics and alcohol should be avoided because of their deleterious effects on upper airway tone. This recommendation is similar to a recommendation of the previous practice parameter paper.

6. Patients should be informed of the risks and complications of laser-assisted uvulopalatoplasty. (Standard)

There are studies specifically evaluating the risks and complications of laser-assisted uvulopalatoplasty (refer to Table 6 in the original guideline document). Any patient electing to undergo laser-assisted uvulopalatoplasty for treatment of snoring should be informed of the potential risks and complications of this procedure. This recommendation is based on the documented risks of laser-assisted uvulopalatoplasty and the American Academy of Sleep Medicine Standards of Practice Committee consensus and is similar to a recommendation of the previous practice parameter paper.

Definitions:

Recommendation Grades

A (Evidence Level I)

Randomized well-designed trials with low-alpha & low-beta errors*

B (Evidence Level II)

Randomized trials with high-beta errors*

C (Evidence Level III)

Nonrandomized controlled or concurrent cohort studies

C (Evidence Level IV)

Nonrandomized historical cohort studies

C (Evidence Level V)

Case series

^{*} Alpha error refers to the probability (generally set at 95% or greater) that a significant result (e.g., p<0.05) is the correct conclusion of the study or studies. Beta error refers to the probability (generally set at 80% or 90% or greater) that a nonsignificant result (e.g., p>0.05) is the correct conclusion of the study or studies. The estimation of beta error is generally the result of a power analysis. The power analysis includes a sample size analysis which projects the size of the study population necessary to ensure that significant differences will be observed if actually present.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS.

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The practice parameters provide clarification of the following issues related to the use of laser-assisted uvulopalatoplasty (LAUP) as a treatment for snoring:

- The correlation of snoring with disease
- The appropriate patient evaluation of a patient who snores
- Laser-assisted uvulopalatoplasty's role in the treatment of obstructive sleep apnea (OSA)
- The effectiveness, potential risks and complications of laser-assisted uvulopalatoplasty

The guideline developer expects these guidelines to have a positive impact on professional behavior, patient outcomes and, possibly health care costs.

POTENTIAL HARMS

Patients who elect to undergo laser-assisted uvulopalatoplasty for the treatment of snoring may be at risk of incurring a delay in the diagnosis of obstructive sleep apnea because snoring may be reduced or eliminated by laser-assisted uvulopalatoplasty.

The potential adverse effects* of laser-assisted uvulopalatoplasty (and associated frequency) are:

- 1. Choking at meals (81%)
- 2. Dysphagia:
 - Temporary (31%)
 - Persistent (5% to 53%)
 - Severe (1%)
- 3. Poor appetite (21%)
- 4. Dry throat (persistent) (16% to 42%)
- 5. Problems drinking (persistent) (16%)

- 6. Globus sensation (persistent) (10% to 25%)
- 7. Increased gag reflex (10%)
- 8. Differences in swallowing (persistent) (6%)
- 9. Dysphonia (mild) (6%)
- 10. Vasovagal episode (1.8%)
- 11. Voice change (temporary) (1.7% to 17.2%)
- 12. Nasal regurgitation:
 - Temporary (1.7% to 10.3%)
 - Persistent (1% to 20%)
- 13. Vomiting (1.5%)
- 14. Bleeding:
 - Non-severe, immediate or delayed postoperative, includes hemoptysis (1% to 8%)
 - Requiring medical attention (0.4% to 1.8%)
- 15. Velopharyngeal insufficiency (Temporary) (0.5% to 3%)
- 16. Loss of taste:
 - Temporary (0.3%)
 - Persistent (5%)
- 17. Scar fibrosis (0.2% to 30%) (100%**):
 - Mild-Moderate (25%)
 - Severe (3%)
- 18. Infection:
 - Bacterial (0.13%)
 - Oral candidiasis (0.4% to 5.3%)
 - Septicemia fatal (0.03% [1/2900])
- * Other than temporary postoperative pain not exceeding 3 weeks duration; temporary defined as equal to or less than one month
- ** Histopathologic study

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These practice parameters define principles of practice that should meet the needs of most patients in most situations. These guidelines should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific care must be made by the physician in light of the individual circumstances presented by the patient and the available diagnostic and treatment options as resources.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Littner M, Kushida CA, Hartse K, Anderson WM, Davila D, Johnson SF, Wise MS, Hirshkowitz M, Woodson BT. Practice parameters for the use of laser-assisted uvulopalatoplasty: an update for 2000. Sleep 2001 Aug 1;24(5):603-19. [57 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1994 (updated 2001 Aug)

GUIDELINE DEVELOPER(S)

American Academy of Sleep Medicine - Professional Association

SOURCE(S) OF FUNDING

American Academy of Sleep Medicine (AASM)

GUI DELI NE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members: Michael Littner MD; Clete A. Kushida MD, PhD; Kristyna Hartse PhD; W. McDowell Anderson MD; David Davila MD; Stephen F. Johnson MD; Merrill S. Wise MD; Maxwell Hirshkowitz PhD; and B. Tucker Woodson MD, FACS.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the American Academy of Sleep Medicine's Standards of Practice Committee and Board of Directors completed detailed conflict-of-interest statements and were found to have no conflicts of interest with regard to this subject.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline is an update of a previously issued version (Practice parameters for the use of laser-assisted uvulopalatoplasty. Standards of Practice Committee of the American Sleep Disorders Association. Sleep 1994 Dec; 17[8]:744-8).

GUIDELINE AVAILABILITY

Electronic copies: Available (in PDF) from the <u>American Academy of Sleep Medicine Web site</u>.

Print copies: Available from the Standards of Practice Committee, American Academy of Sleep Medicine, One Westbrook Corporate Center, Suite 920, Westchester, IL 60154. Web site: www.aasmnet.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 25, 1999. The information was verified by the guideline developer on May 24, 1999. This summary was updated by ECRI on October 22, 2001. The update information was verified by the guideline developer as of November 21, 2001.

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